



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0558]

Compliance Policy Guide Sec. 230.110--Registration of Blood Banks, Other Firms

Collecting, Manufacturing, Preparing, or Processing Human Blood or Blood Products;

Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of the compliance policy guide (CPG) entitled “Sec. 230.110 Registration of Blood Banks, Other Firms Collecting, Manufacturing, Preparing, or Processing Human Blood or Blood Products (CPG 7134.01),” dated June 17, 1974.

DATES: The withdrawal is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Robert L. Hummel, Division of Compliance Policy (HFC-230), Food and Drug Administration, 12420 Parklawn Dr., ELEM-4152, Rockville, MD 20857, 301-796-4510.

SUPPLEMENTARY INFORMATION: FDA issued the CPG entitled “Sec. 230.110 Registration of Blood Banks, Other Firms Collecting, Manufacturing, Preparing, or Processing Human Blood or Blood Products (CPG 7134.01)” on June 17, 1974. We originally issued CPG 7134.01 entitled “Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products,” to provide FDA’s current thinking regarding the registration

required by 21 CFR part 607 of blood banks and other establishments collecting, manufacturing, preparing, or processing human blood or blood products. Since the last update to CPG 7134.01 in 2000, the regulations for blood establishment registration under part 607 have been amended several times. FDA is withdrawing CPG 7134.01 because it is obsolete.

Dated: June 13, 2012.

Dara Corrigan,

Associate Commissioner for Regulatory Affairs.

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